Remarks

The claims under consideration are Claims 1-27.

The Examiner has set forth a restriction requirement asserting that the claims are so linked to form a single general inventive concept under PCT Rule 13.1. Accordingly, restriction under 35 U.S.C. §121 has been required among the following three general groups:

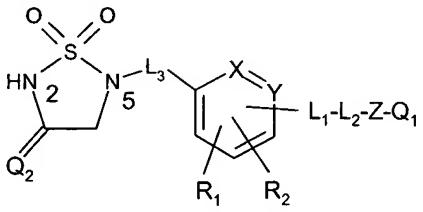
Group I: Claims 1-16, 24-27 drawn to the products of formula (I).

Group II: Claims 17-22, directed to methods of use, e.g., treating diabetes; and

Group III: Claim 23, directed to methods of a different use, e.g., treating atherosclerosis.

In response thereto, the Applicants provisionally elect the invention in Group I, with traverse.

Admittedly, the compounds of Groups I-VI are patentably distinct and that prior art against one of the groups would not be prior art against any of the other groups. However, Applicants do not agree with the Examiner's contention that the compounds of the instant invention either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility and, therefore, restriction of the claims is proper. It is respectfully submitted that a sufficient common structural core exists in that all compounds are mono-substituted 1,1-dioxo-1,2,5-thiadiazolidin-3-one derivatives of the formula



(I)

wherein the single substituent is always located at the 5-position, i.e., at the nitrogen atom between the $S(O)_2$ and the methylene group, and the nitrogen atom at the 2-position is always unsubstituted, i.e., it is a free NH group, or a pharmaceutically acceptable salt thereof. These two features are essential for the desired utility and, therefore, a single inventive concept is involved, and Groups I-VI should be examined together in the same application. As stated in MPEP 803.02:

"Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334

(CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention."

Applicants at the request of the Examiner have further developed the restriction to Group I

Group Ia - Claims 1-16 and 24-27 (in part), directed to compounds of formula (I) and compositions containing compounds of formula (I), wherein X and Y are independently CH; the variable R_1 does not represent heteroaralkyl, heteroaralkoxy, heteroaryloxy, or heterocycle; the variable R_2 does not represent heteroaralkyl, heteroaralkoxy, heteroaryloxy, or heterocycle, and R_1 and R_2 together with the carbon to which R_1 and R_2 are attached not form a fused 5- to 6-membered heteroaromatic ring; the variable L_2 does not represent heteroaryl; the variable L_1 represents a single bond, carbon, CH, nitrogen, oxygen, sulfur, CH_2, or NR_6, and wherein R_6 does not represent heteroaralkyl, and L_1 and L_2 combined together with R_2 and the carbon atoms to which L_1 and L_2 are attached not form an optionally substituted fused 5- or 6-membered heteroaromatic ring, heteroaryl, or heterocycle, and L_1 and L_2 combined together with R_2 and the carbon atoms to which L_1 and L_2 are attached form an optionally substituted fused 5- or 7-membered ring, and wherein the 5- or 7-membered ring does not represent heteroaryl or heterocycle, and the 5- or 7-membered ring is not interrupted with one or two heteroatoms selected from oxygen, nitrogen, and sulfur; the variables Z, Q_1, and L_3 independently do not represent or comprise heterocyclyl, heteroaryl, heteroaralkyl, heteroaralkoxy, heteroaryloxycarbonyl; and the variable Q_2 is as defined in claim 1;

Group Ib: Claims 1-16 and 24-25 (in part), directed to compounds of formula (I) and compositions containing compounds of formula (I), wherein -X=Y- represents sulfur; the variable R_1 does not represent heteroaralkyl, heteroaralkoxy, heteroaryloxy, or heterocycle; the variable R_2 does not represent heteroaralkyl, heteroaralkoxy, heteroaryloxy, or heterocycle, and R_1 and R_2 together with the carbon to which R_1 and R_2 are attached not form a fused 5- to 6-membered heteroaromatic ring; the variable L_2 does not represent heteroaryl; the variable L_1 represents a single bond, carbon, CH, nitrogen, oxygen, sulfur, CH_2, or NR_6, and wherein R_6 does not represent heteroaralkyl, and L_1 and L_2 combined together with R_2 and the carbon atoms to which L_1 and L_2 are attached not form an optionally substituted fused 5- or 6-membered heteroaromatic ring, heteroaryl, or heterocycle, and L_1 and L_2 combined together with R_2 and the carbon atoms to which L_1 and L_2 are attached form an optionally substituted fused 5- or 7-membered ring, and wherein the 5- or 7-membered ring does not represent heteroaryl or heterocycle, and the 5- or 7-membered ring is not interrupted with one or two heteroatoms

selected from oxygen, nitrogen, and sulfur; the variables Z, Q_1, and L_3 independently do not represent or comprise heterocyclyl, heteroaryl, heteroaralkyl, heteroaralkoxy, heteroaryloxycarbonyl; and the variable Q_2 is as defined in claim 1;

Group Ic: Claims 1-16 and 24-25 (in part), directed to compounds of formula (I) and compositions containing compounds of formula (I), wherein -X=Y- represents oxygen; the variable R_1 does not represent heteroaralkyl, heteroaralkoxy, heteroaryloxy, or heterocycle; the variable R_2 does not represent heteroaralkyl, heteroaralkoxy, heteroaryloxy, or heterocycle, and R_1 and R_2 together with the carbon to which R_1 and R_2 are attached not form a fused 5- to 6-membered heteroaromatic ring; the variable L_2 does not represent heteroaryl; the variable L_1 represents a single bond, carbon, CH, nitrogen, oxygen, sulfur, CH_2, or NR_6, and wherein R_6 does not represent heteroaralkyl, and L_1 and L_2 combined together with R_2 and the carbon atoms to which L_1 and L_2 are attached not form an optionally substituted fused 5- or 6-membered heteroaromatic ring, heteroaryl, or heterocycle, and L_1 and L_2 combined together with R_2 and the carbon atoms to which L_1 and L_2 are attached form an optionally substituted fused 5- or 7-membered ring, and wherein the 5- or 7-membered ring does not represent heteroaryl or heterocycle, and the 5- or 7-membered ring is not interrupted with one or two heteroatoms selected from oxygen, nitrogen, and sulfur; the variables Z, Q_1, and L_3 independently do not represent or comprise heterocyclyl, heteroaryl, heteroaralkyl, heteroaralkoxy, heteroaryloxycarbonyl; and the variable Q_2 is as defined in claim 1;

Group Id: Claims 1-16 and 24-25 (in part), directed to compounds of formula (I) and compositions containing compounds of formula (I), wherein -X=Y- represents $-NR_{14}-$; the variable R_1 does not represent heteroaralkyl, heteroaralkoxy, heteroaryloxy, or heterocycle; the variable R_2 does not represent heteroaralkyl, heteroaralkoxy, heteroaryloxy, or heterocycle, and R_1 and R_2 together with the carbon to which R_1 and R_2 are attached not form a fused 5- to 6-membered heteroaromatic ring; the variable L_2 does not represent heteroaryl; the variable L_1 represents a single bond, carbon, CH, nitrogen, oxygen, sulfur, CH_2, or NR_6, and wherein R_6 does not represent heteroaralkyl, and L_1 and L_2 combined together with R_2 and the carbon atoms to which L_1 and L_2 are attached not form an optionally substituted fused 5- or 6-membered heteroaromatic ring, heteroaryl, or heterocycle, and L_1 and L_2 combined together with R_2 and the carbon atoms to which L_1 and L_2 are attached form an optionally substituted fused 5- or 7-membered ring, and wherein the 5- or 7-membered ring does not represent heteroaryl or heterocycle, and the 5- or 7-membered ring is not interrupted with one or two heteroatoms selected from oxygen, nitrogen, and sulfur; the variables Z, Q_1, and L_3 independently do not

represent or comprise heterocyclyl, heteroaryl, heteroaralkyl, heteroaralkoxy, heteroaryloxycarbonyl; and the variable Q_2 is as defined in claim 1.

Group Ie: Claims 1-16 and 24-25 (in part), directed to compounds of formula (I) and compositions containing compounds of formula (I), which compounds are not encompassed in Groups I-An election of a single species is further required.

Applicants provisionally elect Group Ia.

An election of a single species is further required. The Applicants provisionally elect a compound of Example 43, i.e., a compound of formula (I), wherein R_1 is methyl; R_2 is hydrogen; L_1 is a single bond; L_2 is $-(CHR_7)_n-$ wherein n is zero; Z is $-(CH_2)_mO(CHR_8)_r-$ wherein m is zero, R_8 is hydrogen and r is 1; Q_1 is $-C(O)NR_{4a}R_{5a}$ wherein R_{4a} is hydrogen and R_{5a} is benzyl; L_3 is $-(CHR)_s-$ wherein s is zero; Q_2 is oxygen; and X and Y are CH.

As stated in MPEP 803.02:

> "A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type clam should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability."

Therefore, if the provisionally elected species is found allowable, then the Markush-type claim (Claim 1) should be examined fully.

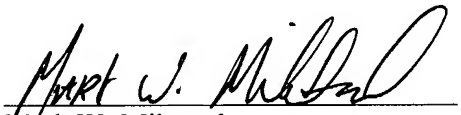
As to the methods of use set forth in Groups II-III, the compounds of the present invention are inhibitors of protein tyrosine phosphatases (PTPases) and, therefore, have the same mode of action. However, inhibition of PTPases inherently results in different effects since the enzymes

are known to mediate a plurality of disease related conditions, e.g., diabetes, insulin resistance and atherosclerosis, and, therefore, the methods are not unrelated even though the patient population may be divergent.

Regarding the Merck & Co European Patent Application (EP 0 501 568 A1), the substituted cyclic sulphamides derivatives disclose act on 5-hydroxytryptamine (5-HT) receptors. The thiazolidon-3-one structure is not disclosed in the EP '568 application. A12 and A13 represent hydrogen or C1-6 alkyl; therefore, the compounds disclosed in the EP '568 application cannot have a carbonyl within sulphamide ring. Applicants respectfully submit that the EP '568 fails to disclose or suggest any compound within the scope of the present claims.

In view of the foregoing, the Examiner is respectfully requested to reconsider the contention that the instant claims lack "unity of invention", withdraw the restriction requirement, and issue an action on the merits of all of the claims in the instant invention.

Respectfully submitted,



Mark W. Milstead
Agent for Applicant
Reg. No. 45,825

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080
(617) 871-4125

Encl.: Petition for three month extension of time

Date: November 13, 2006